K120070

MAR 2 1 2012

510(k) Summary

Date Prepared: March 19, 2012

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA19380 (610) 719-6854
Device Name:	Synthes Variable Angle LCP Elbow System
Classification:	Classification:Class II, §888.3030, Single/multiple component metallic bone fixation appliances and accessories. Product Code: HRS, HWC
Predicate Device:	Synthes 3.5mm LCP Elbow System (K033995) Synthes Small Fragment System (K000684, K011335) Synthes 2.4 mm / 2.7 mm VA-LCP Forefoot /Midfoot System (K100776)
Device Description:	The Synthes Variable Angle LCP Elbow System contains plates intended to treat fractures of the distal humerus and proximal ulna. A variety of plate configurations are included in the system to allow for fixation of multiple fracture patterns. Specifically, the system includes several plate configurations for fixation of the distal humerus which are intended to be used in a two-plate construct where plates are positioned medially and laterally. Additionally, the system includes plates for fixation of the olecranon and proximal ulna. In its entirety, the following plate types are included in the system: • Medial Distal Humerus Plate • Lateral Distal Humerus Plate • Olecranon Plate • Proximal Olecranon Plate • Extra-articular Proximal Ulna Plate The system accepts existing cortical and locking screws as well as new metaphyseal screws, and allows for both dynamic compression and locking through Combi holes. The plates are universally designed for both left and right use and will be offered in both stainless steel and titanium.
Intended Use:	The Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna in adults and adolescents (12-21) in which the growth plates have fused. Specifically, • Distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus. • Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.
Substantial Equivalence:	Both the subject Synthes VA Elbow System and predicate Synthes3.5mm LCP Elbow System and Small Fragment System have similar indications, design characteristics, materials, and performance characteristics. Static and fatigue strength testing, as well as engineering strength analyses, were completed for the plates included in the Synthes Variable Angle LCP Elbow System, demonstrating equal to or greater strength in comparison to the predicate devices and constructs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 1 2012

Synthes
% Ms. Angela F. Lassandro
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K120070
Trade/Device Name: Synthes Variable Angle LCP Elbow System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS, HWC
Dated: January 6, 2012
Received: January 10, 2012

Dear Ms. Lassandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120070

Device Name: Synthes Variable Angle LCP Elbow System

Indications for Use:

The Synthes Variable Angle LCP Elbow System is intended for fixation of fractures of the distal humerus, olecranon and ulna in adults and adolescents (12-21) in which the growth plates have fused. Specifically,

- Distal humerus plates are indicated for intra-articular fractures, comminuted supracondylar fractures, osteotomies, malunions and non-unions of the distal humerus.
- Olecranon and Proximal ulna plates are indicated for fractures, osteotomies, malunions and non-unions of the olecranon and proximal ulna.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120070